Purchasing Controls & Acceptance Activities

FDA Small Business
Regulatory Education for Industry (REdI)
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Objectives

- Provide background on purchasing controls
- Define key terms
- Explain requirements and best practices
- Describe the links between purchasing controls and other QS requirements such as design and acceptance activities
- Review compliance data

Intent of Purchasing Controls

The intent of Sec. 820.50 is to ensure that device manufacturers select only those suppliers, contractors, and consultants who have the capability to provide quality product and services. As with finished devices, *quality cannot be inspected or tested into products or services.*

Preamble to the 1996 QS Regulation, Comment #106

Why Does This Matter?

- Quality of the finished medical device depends on the quality of the components, raw materials and services that went into it.

- Poor Medical Device Quality Can Cause:
  - Injuries from the medical device
  - Recalls
  - Customer dissatisfaction

Why is FDA Concerned about Purchasing Controls

- Inspections and FDA Authority often extend only to the finished device manufacturer.
- FDA does not perform routine inspections of component manufacturers.
- Increasing outsourcing of critical components and manufacturing of entire medical devices.

What is unique about medical devices?

- Wide range in type of supplied *products* and *services*
  - Raw materials, Components, Software, etc.
  - Laboratories, Sterilizers, Calibration, Installers and Service Providers, Auditors, Consultants
- Wide range in complexity in supplied products
  - From components up to finished devices

What else is unique about medical devices?

- Wide range in risk associated with supplied products and services
  - Same supplied product or service may have different risks based on use.
  - Same supplier may have different risks for different supplied product or service.

When are Purchasing Controls applicable?

- Supplied Product
- Supplied Services
- Consultants

Definition: Product

Product includes components, manufacturing materials, in-process devices, finished devices, and returned devices.

§ 820.3(r)

Definition: Component

Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

§ 820.3(c)

Definition: Service

Service (Contractors) means parts of the manufacturing or quality system that are contracted to others, for example, plating of metals, testing, and sterilizing...

Preamble to the 1996 QS Regulation, Comment #102

21 CFR 820.50

Purchasing Control Requirements

Procedures for Purchasing Controls

Establish and maintain procedures to ensure that all purchased or ***otherwise received*** product and services conform to specified requirements

§ 820.50

Suppliers

- External – vendors with no affiliation with the device company
- Affiliated companies – A supplier affiliated with the device manufacturer, a “sister company” or another division. Treated as product from an external vendor
- In-house – only when the supplier is under the same internal audit system.
- Customer supplied product – treated as product from an external vendor

Purchasing Supplier Evaluation

Establish **requirements**, including **quality requirements**, that **suppliers**, **contractors** and **consultants** must meet

§ 820.50(a)

Purchasing Evaluation & Selection

Evaluate and select potential suppliers, contractors, and consultants on the basis of their **ability to meet specified requirements**, including quality requirements. The evaluation shall be documented.

§ 820.50(a)(1)

Type/Extent of Control & Records

- Define the **type and extent of control** to be exercised **over product, services, suppliers, contractors, and consultants** based on results of evaluation.

  § 820.50(a)(2)

- Establish and maintain records of acceptable suppliers, contractors, and consultants

  § 820.50(a)(3)

Control Over Suppliers

... A finished device manufacturer may choose to provide greater in-house controls to ensure that products and service meet requirements, or may require the supplier to adopt measures necessary to ensure acceptability, as appropriate.

Preamble to the 1996 QS Regulation, Comment #99

Purchasing Data

- Establish and maintain data that clearly describe or reference specified requirements, including quality requirements, for purchased or otherwise received products and services
- Approve in accordance with Document Controls in § 820.40

§ 820.50(b)

Purchasing Data

- Include, where possible, an agreement that suppliers, contractors, and consultants will notify the manufacturer of changes in the product or service so the manufacturer can determine the effect of changes on the finished device

  § 820.50(b)

Ongoing Supplier Reviews

The capability of the product or service suppliers should be *reviewed at intervals consistent with the significance of the product or service provided* and the review should demonstrate conformance to specified requirements.

Preamble to the 1996 QS Regulation, Comment #103

Ongoing Communication

- Supplier's complaint handling system and discussion of any defects in product that could result in problems with the device.
- Supplier's willingness to provide information when the device manufacturer is performing a CAPA where the device defect my be due to a problem with the supplier's product.

Guidance

- Global Harmonization Task Force (GHTF)

  Title: *Quality Management System- Medical Devices- Guidance on Control of Products and Services Obtained from Suppliers*

  Authoring Group: **GHTF Study Group 3**

  Effective Date: December 11, 2008

Six Steps to Supplier Controls

Typically these six steps are involved in establishing controls for products and services obtained from suppliers:

1. Planning
2. Selection of potential supplier/s
3. Evaluation/acceptance of supplier
4. Finalization of responsibilities and controls
5. Delivery, measurement and monitoring
6. Communication including the CAPA process

Purchasing Controls Link to Other Quality System Requirements

- Design Controls (21 CFR 820.30)
  - Product design drives purchasing decision-making
- Acceptance Activities (21 CFR 820.80)
  - In-house Acceptance activities complement supplier controls

Purchasing Controls Link to Design Controls

… *the quality of a product or service is established during the design* of that product or service, and achieved through proper control of the manufacture of that product or the performance of that service…

Preamble to the 1996 QS Regulation, Comment #106

Specifications

- Specifications for the device are determined in Design Controls, (21 CFR 820.30)
  - Design Inputs ensure that design requirements relating to the device are appropriate and address intended use
  - Design Outputs must contain or make reference to acceptance criteria and identify essential design outputs

Suppliers, You & Risk

Use Risk Analysis and strike a balance for controlling supplied product and service through a combination of purchasing controls and acceptance activities.

Acceptance Activities

- Establish and maintain procedures for acceptance activities of incoming product, (21 820.80)
- Acceptance activities include:
  1. Inspections, Tests and other verification activities
  2. Documenting acceptance or rejection

Purchasing Controls and Acceptance Activities, cont.

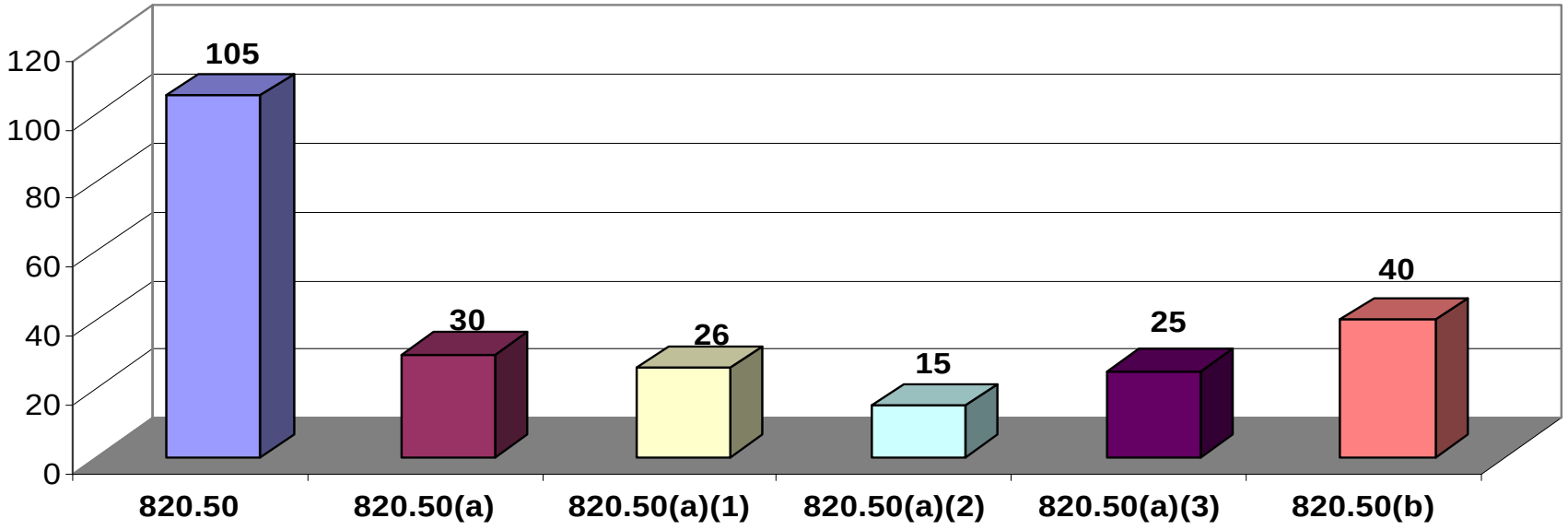
... The extent of incoming acceptance activities can be based, in part, on the degree to which the supplier has demonstrated a capability to provide quality products or services.

Preamble to the 1996 QS Regulation, Comment #106

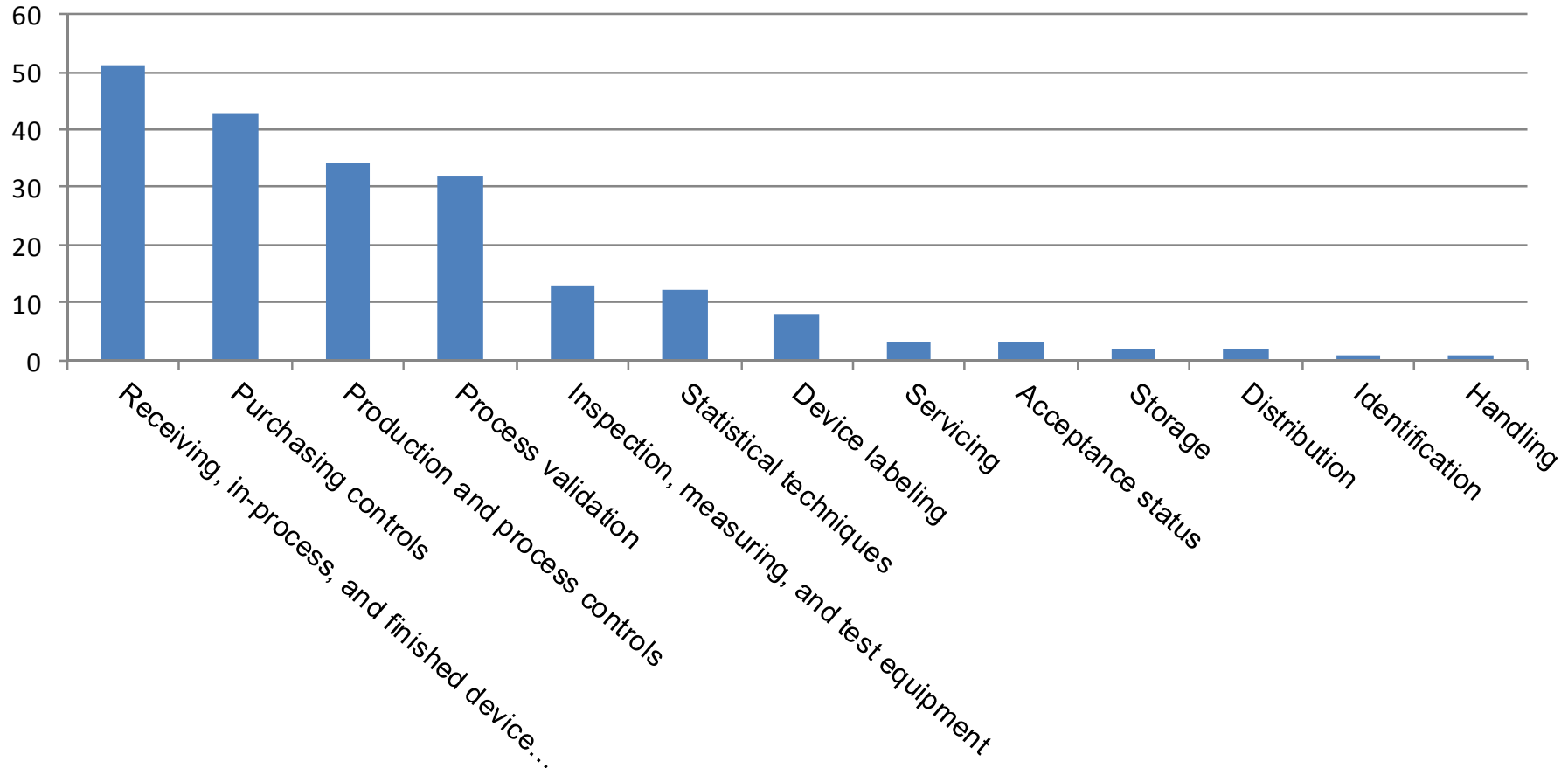
2011 FDA Inspectional Data FDA 483 Observations

- Source of data - FDA's Turbo EIR database
- Time frame 1/1/2011 to 12/31/2011
- **3995** observations cited for 21 CFR 820 deficiencies out of **3153** inspections
- **241** observations cited for Purchasing Controls

Purchasing Controls
FDA 483 Observations 2011



P&PC Warning Letter Cites 2011



Purchasing Controls Warning Letter Data

	2009	2010	2011
820.50	12	17	26
820.50(a)	4	3	6
820.50(a)(1)	5	3	3
820.50(a)(2)	0	2	3
820.50(a)(3)	3	0	3
820.50(b)	4	4	4
Total Cites	**27**	**29**	**45**

Industry Assistance
CDRH Resources

- Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)
  - Education for the Medical Device Industry
  - **Phone**: 1-800-638-2041 or 301-796-7100
  - **Email**: dsmica@fda.hhs.gov

THANK YOU